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103D CONGRESS
2D SESSION

H. R. 3878

To amend the Public Health Service Act to establish a requirement of informed consent regarding the use of human subjects in research conducted or supported by the Federal Government, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 23, 1994

Mr. COOPER (for himself, Mr. CLEMENT, Mr. TANNER, Mr. GORDON, Mr. DUNCAN, Mr. QUILLEN, Mr. FORD of Tennessee, Mrs. LLOYD, and Mr. SUNDQUIST) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To amend the Public Health Service Act to establish a requirement of informed consent regarding the use of human subjects in research conducted or supported by the Federal Government, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Federal Research Informed Consent Act''.

SEC. 2. REQUIREMENT OF INFORMED CONSENT REGARDING USE OF HUMAN SUBJECTS IN FEDERALLY QUALIFIED RESEARCH.

(a) IN GENERAL.—Section 491 of the Public Health Service Act (42 U.S.C. 289) is amended by adding at the end the following subsection:

''(c) REQUIREMENT OF INFORMED CONSENT REGARDING HUMAN SUBJECTS.—

''(1) IN GENERAL.—Subject to paragraph (2), the Secretary shall by regulation establish the requirement that, in federally qualified research in which any human subject is to be used, an individual may not be used as a subject unless the principal researcher obtains the informed consent of the individual to serve as a subject.

''(2) EXEMPTED CATEGORIES OF RESEARCH.—

''(A) With respect to the requirement of paragraph (1) that informed consent be obtained, the Secretary may, in issuing regulations under such paragraph, establish such exempted categories of research as the Secretary determines to be appropriate. The regulations may not authorize any waiver of the applicability of the requirement to a research activity that is not within such a category.

''(B) In the case of a particular research activity, the Secretary is responsible for approving or disapproving the activity as qualifying for an exemption under subparagraph (A).

''(C) If under subparagraph (B) the Secretary approves an exemption, the Secretary shall submit to the congressional committees of jurisdiction a notification that the exemption has been approved (together with a description of the circumstances). In the case of classified materials, the notification shall be submitted to the committees, and reviewed by the committees, in accordance with any applicable requirements for such materials.

''(D) An exemption approved by the Secretary under subparagraph (B) takes effect upon the expiration of the 60-day period beginning on the date on which the notification regarding the exemption is submitted under subparagraph (C).

''(3) CRITERIA REGARDING PROVISION OF CONSENT.—In issuing regulations under paragraph (1), the Secretary shall establish requirements for obtaining informed consent, including requirements regarding the information to be provided to the pro-

spective research subject and requirements regarding documentation of the informed consent of such subject.

''(4) NONCOMPLIANCE.—

''(A) An individual aggrieved as a result of a violation of the requirement under paragraph (1) may obtain appropriate relief through a civil action, including damages, equitable relief, and a reasonable attorney's fees and costs. Damages in such an action may include damages other than actual damages.

''(B) With respect to a civil action under subparagraph (A), if the research involved allegedly was conducted by the United States, the defendant shall be the United States. The United States district courts have exclusive original jurisdiction of actions described in the preceding sentence, and such actions may be commenced in a judicial district only in accordance with applicable law on the venue of civil actions.

''(C) With respect to a civil action under subparagraph (A), if the research involved allegedly was conducted by a State, the defendant shall be the head of the State agency involved. Actions described in the preceding sentence

may be commenced in any court of competent jurisdiction. For purposes of this subparagraph, a State is not immune under the Eleventh Amendment of the Constitution of the United States from a civil action under subparagraph (A) in Federal court.

''(D) With respect to a civil action under subparagraph (A), if the research involved allegedly was not conducted by the United States or by a State, the entity that allegedly did conduct the research shall be the defendant. Actions described in the preceding sentence may be commenced in any court of competent jurisdiction.

''(E) With respect to the death of an individual who is aggrieved for purposes of subparagraph (A), the cause of action survives the individual and the civil action under such subparagraph may be commenced only by a personal representative of the individual.

''(F) With respect to limitations on commencing a civil action under subparagraph (A)—

''(i) the civil action may not be commenced after the expiration of the 5-year

period beginning on the date on which the individual (or the personal representative, as the case may be) receives notice of the alleged facts with respect to which the individual is aggrieved; and

''(ii) notwithstanding clause (i), the civil action may not be commenced after the expiration of the 50-year period beginning on the date on which the individual dies.

''(5) PREEMPTION.—This subsection supersedes any private cause of action under the laws of a State arising as a result of the use of an individual as a subject in federally qualified research without the consent of the individual.

''(6) DEFINITIONS.—For purposes of this subsection:

''(A) The term 'federally qualified research' means—

''(i) any research conducted or supported by the Federal Government; and

''(ii) any research regulated by the Federal Government, other than research which is only incidentally regulated.

''(B) The term 'principal researcher', with respect to federally qualified research, means the individual with the principal responsibility for conducting the research.''.

(b) STYLISTIC CONFORMING AMENDMENTS.—Section 491 of the Public Health Service Act (42 U.S.C. 289) is amended—

(1) in subsection (a), by striking ''(a) The Secretary'' and inserting ''(a) INSTITUTIONAL REVIEW BOARDS.—The Secretary''; and

(2) in subsection (b)—

(A) by striking ''(b)(1) The Secretary'' and inserting the following:

''(b) ETHICS GUIDANCE PROGRAM.—

''(1) IN GENERAL.—The Secretary''; and

(B) in paragraph (2), by striking ''(2) The Secretary'' and inserting the following:

''(2) RESPONSE RESPECTING VIOLATIONS.—The Secretary''.

SEC. 3. EFFECT ON EXISTING REGULATIONS; EFFECTIVE DATE REGARDING CAUSES OF ACTION.

(a) EFFECT ON EXISTING REGULATIONS.—With respect to the provisions of part 46 of title 45, Code of Federal Regulations (relating to the protection of human subjects), as in effect on the date of the enactment of this

Act, the legal status of such provisions is affected by the amendment made by section 2(a) only to the extent that any such provision is inconsistent with the amendment.

(b) EFFECTIVE DATE REGARDING CAUSES OF ACTION; APPLICABLE PROVISIONS.—The requirement established under section 491(c)(1) of the Public Health Service Act (as added by the amendment made by section 2(a) of this Act) is effective in the case of any violation of the requirement occurring on or after the date of the enactment of this Act, without regard to the date on which final regulations under such section take effect. For purposes of the preceding sentence, in the case of a cause of action accruing before such regulations take effect—

(1) a defendant is liable, subject to paragraphs (2) and (3), if the principal researcher involved (as defined under such amendment) failed to obtain informed consent in accordance with the provisions of part 46 of title 45, Code of Federal Regulations (relating to the protection of human subjects), as in effect on the date of the enactment of this Act;

(2) it is a defense that the Secretary of Health and Human Services—

(A) determined that the research activity involved was within one of the categories of re-

search described in section 46.101(b) of such part;

(B) determined that the research activity otherwise was not covered by the policy; or

(C) with respect to informed consent, waived the applicability of the requirements involved; and

(3) it is not a defense (except as provided in paragraph (2)) that—

(A) for purposes of section 46.101(a) of such part, the Federal department or agency involved did not take action to make the policy applicable;

(B) for purposes of section 46.101(c) of such part, the department or agency head determined that the research activity was not covered by the policy; or

(C) for purposes of section 46.101(i) of such part, the department or agency head waived the applicability of some or all of the provisions of the policy.

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